ORIGINAL

SEALED

Jonathan Hamer ex rel. UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE STATE OF MICHIGAN, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE STATE OF WISCONSIN, THE COMMONWEALTH OF MASSACHUSETTS, THE COMMONWEALTH OF VIRGINIA, THE DISTRICT OF COLUMBIA, THE CITY OF CHICAGO, THE STATE OF CONNECTICUT, THE STATE OF COLORADO, THE STATE OF MARYLAND, THE STATE OF IOWA, and THE STATE WASHINGTON Plaintiffs, v. Bond Pharmacy, Inc., is a Delaware corporation, trading as Advanced Infusion Solutions Defendant	3-23CV1472-BG QUI TAM COMPLAINT PURSUANT TO THE FALSE CLAIMS ACT, 31 U.S.C. §3729 ET SEQ.

QUI TAM COMPLAINT

1. Plaintiff and Relator Jonathan Hamer ("Relator") hereby files this qui tam complaint pursuant to the False Claims Act, 31 U.S.C. § 3729 et seq. ("FCA") on behalf of the United States and the state government entities ("State Plaintiffs") under the individual false claims acts identified herein, as well as for himself individually under § 3730(h) of the FCA.

2. As required, Relator has provided a disclosure statement in accordance with § 3730(e)(4)(B) and § 3730(b)(2) of the FCA and the relevant provisions of the State Plaintiffs' individual false claims acts identified herein.

3. The footnotes contained in this qui tam complaint should be read and considered as part of the allegation set forth in such paragraphs.

I. SUMMARY OF CLAIMS

A. Background and Overview

4. Defendant Bond Pharmacy, Inc., is a Delaware corporation, trading as Advanced Infusion Solutions ("AIS"). AIS provides, inter alia, targeted drug delivery ("TDD") for drug medications it "compounds" through infusion therapy, by dispensing and administering its compounded medication with implantable intrathecal pumps manufactured by a third party.

5. Relator was hired in early 2018 by AIS and served as Director of Pharmacy and eventually Pharmacist in Charge ("PIC") of the AIS Dallas, Texas facility from its opening through the Summer of 2021.

6. Relator observed repeated areas of regulatory noncompliance, including, inter alia, faulty construction methods and conditions that lead to systematic unsafe conditions as well as a chronic failure to maintain the Dallas facility in a safe and sterile condition as required by applicable laws noted herein. AIS was, and has been aware, of these conditions.

7. Collectively, this malfeasance has caused significant and substantial unsterile and unsafe conditions in the Dallas facility in general and in the "clean room" [1] where the drug

[1] Clean rooms are classified according to the cleanliness level of the air inside the controlled environment measured by the size of particles per cubic meters of air. The primary authority in the United States for classification of clean rooms is the ISO classification system referred to as ISO 14644-1. This ISO standard includes these clean room classes: ISO 1, ISO 2, ISO 3, ISO 4, ISO 5, ISO 6, ISO 7, ISO 8 and ISO 9. ISO 1 is the "cleanest"

compounding occurs, leading to adulteration of the drugs and loss of efficacy of the drugs being compounded.

8. "Drug compounding" refers to "the process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002). Though a compounded drug qualifies as a "new drug" under the Food, Drug and Cosmetic Act (FDCA) 21 U.S.C. § 321(p), the Food and Drug Administration ("FDA") has historically left regulation of compounded drugs to the states. Over time, however, FDA grew concerned that some pharmacies were compounding drugs at levels that rendered the pharmacies akin to drug manufacturers.

9. To address these concerns, Congress added Section 503A to the FDCA. *See* 21 U.S.C. § 353a ("Section 503A"). Section 503A sets forth certain conditions that must be satisfied for compounded drugs to be exempt from the vast regulatory framework in the FDCA that would otherwise govern new drugs. First, there is a general exemption for drugs that are "compounded for an identified individual patient based on the receipt of a valid prescription or a notation." Section 503A then imposes additional requirements for such compounded drugs that are distributed interstate. Specifically, a drug may be compounded pursuant to Section 503A's general exemption only if it falls into one of two categories:

> (B) such drug product is compounded in a State—
>
> > (i) that has entered into a memorandum of understanding ("MOU") with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate

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class and ISO 9 is the "dirtiest" class. Even if it is classified as the "dirtiest" class, the ISO 9 clean room environment is cleaner than a regular room. The most common ISO clean room classes are ISO 7 and ISO 8.

> investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or
>
> (ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

9. An MOU under Section 503A describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FDCA requiring: (1) compliance with current good manufacturing practice. (21 U.S.C. 351(a)(2)(B)) ("Section 501(a)(2)(B)"); (2) labeling with adequate directions for uses (21 U.S.C. 352(f)(1)) ("Section 502(f)(1)"); (3) FDA approval prior to marketing (21 U.S.C. 355) ("Section 505").

10. AIS has obtained licenses in all 50 states, representing itself in the license applications and registration as meeting the conditions to be a Section 503A pharmacy. As such, AIS as a Section 503A facility must compound its drug products in accordance to patient specific prescriptions and is required by the state boards of pharmacy to comply with US Pharmacopeia ("USP") guidelines.

11. USP is an independent, scientific nonprofit organization focused on standards to build trust in the supply of safe, quality medicines. USP General Guidelines, Chapter 795 (non sterile), Chapter 797 (sterile) and Chapter 800 (hazardous). These standards apply to all healthcare personnel who receive, prepare, administer, transport or otherwise come in contact with hazardous drugs and all the environments in which they are handled.

12. Chapter 800 describes the specific requirements and responsibilities of personnel handling hazardous drugs; facility and engineering controls; procedures for deactivating, decontaminating and cleaning; spill control; and documentation.

13. Compounded medications made without the guidance of standards maybe sub-potent, super-potent or contaminated, exposing patients to significant risk of adverse events or even death. USP developed standards for compounding sterile medications to help ensure patient benefit and reduce risks such as contamination, infection or incorrect dosing. Specifically, USP Chapter 797 set forth standards and guidelines for pharmaceutical compounding of sterile preparations to ensure the quality and safety of compounded sterile drug preparations. These are medications that are administered intra-ocular and intrathecal. USP Chapter 797 standards apply to all pharmacies that produce compounded sterile preparations ("CSPs"), including those in hospitals, retail and standalone settings. USP Chapter 797 provides the standards under which regulatory agencies, particularly the state-level departments of public health and board of pharmacy, can pursue pharmacies for unsafe compounding practices. Chapter 797 was developed to prevent patient harm and fatalities from microbial contamination, excessive bacterial endotoxins, large content errors in the strength of correct ingredients, and the inclusion of incorrect ingredients in CSPs.

14. Violations of the FDCA by AIS also include adulterated drug products. Drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have been contaminated with filth, or rendered injurious to health, causing AIS products to be adulterated in violation of Section 501(a)(2)(A) of the FDCA [21 United States Code (USC) 351(a)(2)(A)]. For example, there were poor aseptic practices, including an operator not disinfecting or changing gloves prior to introducing them into an ISO

5 area from an ISO 7 area and after touching non-sterile material. Multiple operators with non-sterile gowning and exposed their facial skin were observed leaning into the ISO 5 work area. AIS also exposed stock solutions, intended to be sterile, to lower than ISO 5 quality air. This included the storage of said solutions in an unclassified area for further use after the container closure system had been punctured multiple times, and therefore compromised, throughout the assigned expiry period. It is a prohibited act under Section 301(k) of the FDCA to do any Act with respect to a drug if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

In order to maintain 503A exempt status, AIS must:

- Comply with the standards and guidelines in USP, Chapters 797 and 800 (collectively "USP Standards").
- Comply with state board of pharmacy regulations.
- Compound sterile medications must be dispensed as patient specific

Other requirements include (i) labeling in compliance with the Drug Quality and Security Act ("DQSA"), and (ii) registration with each state board of pharmacy and Drug Enforcement Agency ("DEA").

The DEA license for AIS' Dallas facility was filled out in Relator's name with his e-signature without his knowledge or approval.

16. By virtue of the foregoing, AIS has materially failed to adhere to the USP Standards as well as sanitary and sterile conditions described and required herein. As such, it is not exempt under Section 503A. The violations described herein are significant, systematic and substantial and have given rise to actual discrepancies in the composition or functioning of the drugs, giving rise to FCA liability on the part of AIS.

17. In addition, some compounding deficiencies by AIS can affect, and have affected, the strength, purity and quality of the drugs essentially rendering them "worthless" and not eligible for payment by the Government.

18. Separate and apart from its conduct referred to in paragraphs 5 through 17, AIS also engaged in a scheme to increase referrals from health care providers by offering the payment of fees to sit on its Medical Advisory Boards ("MABs") in violation of the Federal Anti-Kickback Act, 42 U.S.C. § 1320 et seq., ("AKA"). Essentially, AIS caused false claims to be submitted to the United States by inducing healthcare providers to prescribe AIS compounded drug medication for reimbursement from federal and state healthcare payors in violation of the AKA. Specifically, AIS uses MABs to purportedly gather information from its physician members. AIS used MABs not for any legitimate educational program for the medical community and the pharmaceutical companies, but instead used MABs, which lacked educational merit, to induce providers, by conferring payments and other benefits to providers prescribing their products. Purported meetings of the MABs were accompanied by other inducements shall as free travel, lodging and meals.

19. AIS's actions in regard to MABs violated the express and implied certifications by AIS of compliance with applicable law in violation of the FCA. The violations and false certifications are material and were made by AIS knowingly.

II. THE PARTIES

A. Relator

20. Relator Jonathan Hamer was hired in early 2018 and served as Director of Pharmacy and eventually PIC of AIS, Dallas facility from its opening through summer of 2021. He was then promoted to the executive side and no longer in the pharmacy. Relator had asked to no longer be in the legal designation of PIC due to significant compliance, quality and legal issues that were not prioritized or addressed appropriately for him to feel comfortable in that role.

21. By March 2022, AIS' Dallas facility was in significant disarray as multiple staff had resigned over compliance and workplace conditions. Relators' employment was then terminated by AIS in March 2022 under the pretext of a "reduction in work force."

B. AIS

22. Bond Pharmacy, Inc., is a Delaware corporation, operating under the assumed name of as Advanced Infusion Solutions ("AIS"). AIS has offices at 623 Highland Colony Pkwy., Suite 100, Ridgeland, Mississippi 39157- 6077 and 18451 Dallas Parkway, Suite 150, Dallas, Texas 75287.

23. AIS is a provider of TDD and infusion care, in the latter case as a home infusion therapy service provider. Previously, AIS had also provided ophthalmic services.

24. AIS provides patients with a specific subset of infusion therapy by administering and dispensing compounded drug medication through implantable intrathecal pumps. Intrathecal pumps are surgically placed under a patient's skin and filled with medication that the pump delivers through a catheter to the intrathecal space of the spinal column. These pumps can infuse

the patient's medication daily for up to 120 days and routinely even longer that 120 days before needing to be refilled.

25. AIS is licensed to operate in all 50 states. AIS offers patient-specific, in-home pump care and care coordination services as well as intravenous ("IV") and subcutaneous ("SubQ") immunoglobulin therapies. Relevant here is AIS' intrathecal TDD. Relator was hired to operate AIS' Dallas TDD operation.

III. JURISDICTION

26. This action arises under the FCA, 31 U.S.C. § 3729 et seq., and the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 1345.

27. This Court also has supplemental jurisdiction over the claims brought by Relator on behalf of the State Plaintiffs under their state FCAs, pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b), and pursuant to 28 U.S.C. § 1367(a) also over Relator's individual claims.

IV. VENUE

28. Venue in this district is proper pursuant to 31 U.S.C. §3732(a) and 28 U.S.C. §1391(b) and (c) since AIS transacts business in this district and/or one or more of the acts at issue occurred in this district.

V. FEDERAL AND STATE LAWS

A. The Federal Health Care Programs

29. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C.§ 1395 et seq. ("Medicare"), is a health insurance program administered by the United States that is funded by federal taxpayer revenue. The program is overseen by the United States Department of Health and Human Services ("HHS"). Medicare is a health insurance program that provides for the payment of prescription drugs, hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of Medicare.

30. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396-1396v ("Medicaid"), is a health insurance program administered by the United States and the various individual States and is funded by state and federal taxpayer revenue. The Medicaid Program is overseen by HHS. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

31. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, et seq. provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the uniformed services of the United States and to spouses and children of active duty, retired and deceased members of such uniformed services. The program is administered by the United States Department of Defense and funded by the United States. TRICARE pays for, among other items and services, prescription drugs for its beneficiaries.

32. The United States, through its Departments of Defense and Veterans Affairs, Bureau of Prisons, Native and American Indian Health Services, and Public Health Service maintains and operates medical facilities, including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise.

33. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. Together the programs described in paragraphs 29 through 32 shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs."

B. The False Claims Act

34. The FCA, 31 U.S.C. § 3729(a)(1),[2] makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty.

35. The FCA, 31 U.S.C. § 3729(a)(2), makes "knowingly" making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the United States sustains and a civil monetary penalty.

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[2] On May 22, 2009, the Fraud Enforcement and Recovery Act ("FERA") was enacted into law which, inter alia, amended the False Claims Act. Part of the amendment renumbered certain sections. Under FERA, effective May 22, 2009 3729(a)(1) became 3729(A)(1). Likewise, 3729(a)(2) became 3729(A)(2) and 3729(a)(3) became 3729(A)(3) . Since the allegations include a time period before and after May 22, 2009, references are to be applicable sections.

36. The FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States provides any portion of the money or property which is requested or demanded, or if the United States will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

C. The State False Claims Acts

37. As specified above, the State Plaintiffs have enacted state false claims acts similar to the FCA, permitting a private person such as Relator to bring suit to recover on behalf of each of the States from persons that knowingly submit false claims to the States or engage in related misconduct, and providing for awards to a private person bringing the action if the States prevail in the actions.

38. As set forth below, several states have passed false claims acts (the "State False Claims Acts") legislation, which in most instances closely tracks the Federal FCA. These include the following states: The State Of California, The State Of Delaware, The State Of Florida, The State Of Georgia, The State Of Hawaii, The State Of Illinois, The State Of Indiana, The State Of Louisiana, The State Of Michigan, The State Of Montana, The State Of Nevada, The State Of New Jersey, The State Of New Mexico, The State Of New York, The State Of Oklahoma, The State Of Rhode Island, The State Of Tennessee, The State Of Texas, The State Of Wisconsin, The Commonwealth Of Massachusetts, The Commonwealth Of Virginia, The District Of Columbia, The City Of Chicago, The State Of Connecticut, The State Of Colorado, The State Of Maryland, The State Of Iowa, And The State Washington. These State False Claims Acts apply to the state portion of Medicaid fraud losses caused by false Medicaid claims within the joint federal-state funded Medicaid program. Each of the statutes listed above contains *qui tam*

provisions of the State False Claims Acts governing, *inter alia*, a relator's right to claim a share of a state's recovery.

D. Section 503A of the FDCA

39. Section 503A, added to the FDCA by the Food and Drug Administration Modernization Act of 1997 and amended by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemption from the FDCA.

40. As described herein previously. Section 503A sets forth certain conditions that must be satisfied for compounded drugs to be exempt from the vast regulatory framework that would otherwise govern new drugs.

41. AIS has obtained licenses in all 50 states representing itself in the license applications and registration as meeting the conditions to be a Section 503A pharmacy. As such, AIS as a 503A facility must compound its drug products in accordance to patient specific prescriptions and is required by the state boards of pharmacy to comply with USP Standards previously described.

E. The Anti-Kickback Statute

42. The Medicare, Medicaid and Anti-Kickback Act ("AKA") 42 U.S.C. §1320a-7b(b), makes it illegal to:

> *offer,* receive, or solicit *any remuneration*, kickback, bribe, or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from any person in order *to induce such person to purchase*, lease, or order, or to arrange for or recommend the purchasing, leasing, or ordering of *any good, service, or item for which payment may be made in whole or in part under a Federal Health Care Program.*

Many states have similar laws pertaining to the Medicaid program.

43. The AKA has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Kats,* 871 F.2d 105, 108 (9th Cir.1989); *United States v. Greber,* 760 F.2d 68, 69 (3d Cir.1985); *see United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.,* 874 F.2d 20, 33 (1st Cir.1989) ("The key to a Medicare Fraud case is the reason for the payment—was the purpose of the payments primarily for inducement.")

44. Congress prohibits pharmaceutical companies from compensating healthcare providers to induce them to prescribe often more expensive drugs paid by federal and state treasuries. Mindful of this bar, marketing to persuade healthcare providers to serve on their internal advisory boards may violate the AKA.

45. Preservation of the public fisc would be undermined if a provider could engage in conduct warranting exclusion from the program altogether yet still demand payment until the time of formal exclusion.

46. The AKA is intended not only to prohibit but also to prevent such fraudulent conduct. The AKA's "legislative history also suggests a deterrent, and thus punitive, purpose."

H.R.Rep. No. 95–393, pt. 2, at 44, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3040, 3047, 3050 (stating that the AKA was enacted to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs"). If providers could demand payment for claims resulting from kickback violations, then the AKA would be meaningless legislation.

47. Compliance with the AKA clearly factors into the government's reimbursement decision; not only is the government unwilling to pay a claim that is the product of criminal conduct under the AKA, but also to submit such a claim for reimbursement is in effect to ask the government to fund criminality retroactively, a result specifically proscribed by the AKA. *See* 42 U.S.C. § 1320a–7b(b).

VI. ALLEGATIONS OF THE FALSE CLAIMS

A. The Deficiencies at the AIS Dallas Facility

48. The AIS Dallas facility was built on non-sealed porous ground. The Chief Quality Officer ("CQO"), who at the time was the Chief Operating Officer ("COO"), Michael Ford ("Ford"), was aware of this significant problem. Instead of correcting the condition, Ford directed the contractor to proceed and signed off on a waiver absolving the contractor of any liability when this problem was brought to his attention.

49. Relator learned from several of the original construction crew and engineers as well as clean room specialists that Ford was told water would seep through the ground into the Dallas facility. These concerns were dismissed by senior management at AIS for years.

50. As warned, water, sewage, and mold seeped through the floor of the Dallas facility, causing putrid odor and bubbling of the floor. Not only is this considered an "insanitary

condition" according to the FDA, to continue to compound medication, this may have contributed to reported patient illnesses during this time and which have never been disclosed.

51. Sewer waste has continuously been backed up into the AIS Dallas facility on multiple occasions and then covered up. It is a well-known occurrence that at certain times of day and certain temperatures, the facility reeked of human waste.

52. Much like the floor, the walls of the clean room at the Dallas facility were disintegrating for months, creating another "an insanitary condition," during the compounding of many syringes.

53. In addition to informing AIS management of the problems referred to in paragraphs 48 through 52, Relator also reported the sanitary conditions to outside consulting/inspections groups so that they would put it in their report to force leadership to deal with it.

54. At the AIS Dallas Facility, there were and still are material violations of USP Standards Chapter 795, 797 and 800. These include:

1. Clothes and gloves are not inspected for rips and tears routinely during compounding.

2. There is no complete physical separation, either fixed or non-fixed, of areas where blood products are handled from areas where non-blood products are handled. This is particularly egregious where compounding activities require the manipulation of a patient's blood or other biological matter.

3. The airflow visualization studies performed by Air Safe on February 2, 2021 demonstrated that airflow was not shown from the entry point (approximately an

inch below the HEPA filter diffuser screen) and airflow was not shown from the above IV bar to the direct compounding area.

4. Training at the AIS Dallas facility does not comply with OSHA 1910.120.

5. There is no policy or procedure for spill management.

6. The work surfaces of the CPEC are often contaminated between the compounding of different HDs and in between compounding serums. The purpose of the decontamination is to reduce the likelihood that patients will be exposed to HDs other than those that are prescribed to them or being exposed to serum that is not theirs. This is not currently occurring nor is it prescribed.

7. There is a failure to properly label, pack, and transport the disposals of Hds.

B. Compounding of Commercially Available Products

55. One of the conditions that must be met for a compounded drug product to qualify for exemption under Section 503A of the FDCA is that it must be compounded by a licensed pharmacist or a licensed physician who "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product." The statute further states that "the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug."

56. Relator verbally and in writing raised concerns that AIS compounded drug medications were "essentially copies of commercially available medications," as defined by the

FCA, after Relator joined AIS. Specifically, Relator objected to AIS management that they, in essence operating improperly as a 503B Facility for which they were not licensed. Examples of these drugs were, inter alia, morphine sulfate, fentanyl citrate, and hydromorphone HCI. These included the same patients getting prescriptions as many as eight times for "one-time eye surgeries."

57. Drug products were compounded at >1000x the amount needed to serve AIS customers.

C. Illegal Kickbacks as an Inducement to Providers

59. On paper, AIS implemented MABs to "create an intimate forum where compounding issues, clinical data, and patient care could be debated."

60. In practice, however, AIS used MABs as a "sales tactic" to expand AIS's market presence. AIS paid doctors to attend MABs and offered valuable meals and entertainment.

61. AIS invited "targeted physicians" from "key accounts" to attend advisory boards.

62. AIS controlled the content of MABs. AIS used MABs as an opportunity to market its products instead of allowing doctors to freely discuss clinical data and patient care.

63. AIS violated the AKA by paying doctors kickbacks to prescribe its compounded drug medications, for which the doctors submitted claims for payment to the federal government. AIS's scheme involved offering or paying "remuneration." At least one purpose of the scheme was to "induce" doctors to prescribe more and AIS possessed the requisite scienter.

VII. THE FCA AND FALSE CERTIFICATIONS

A. Implied Certification

65. The FCA is "intended to reach all types of fraud, without qualification, that might result in financial loss to the government." *United States v. Neifert White*, 390 U.S. 228, 232 (1968). Relator alleges that AIS violated the FCA by causing the submission of false claims[3] all in violation of 31 U.S.C. § 3729(a)(1) (A) and (B).

66. A legally false FCA claim is based on a 'false certification' theory of liability." A claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation which is material to the government's decision whether to make payment for the goods or services.

67. Within the theory of false certification, there are two further categories: express and implied false certification. A defendant violates the FCA by express false certification when, in conjunction with a request for federal funds, it certifies that it is in compliance with regulations that are requirements for payment.

68. An FCA violation occurs under implied false certification when a Defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose noncompliance with a statutory, regulatory or a contractual requirement. In these circumstances, liability may attach if the omission renders

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[3] The FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

those representations misleading. This is substantially the same scenario and facts presented. *United States ex rel. Escobar*, 579 U.S.___, 2016 WL 3317565, slip op., No. 15-7 (June 16, 2016).

69. The false statements contained in AIS certifications as to its eligibility and compliance with Section 503A to the FDA and state pharmacy boards and with the USP Standards represents a false implied certification.

70. A false certification (express or implied) establishes the "falsity" of a claim under the FCA. This was emphasized by Congress in the 1986 Amendments to the FCA, stating "each and every claim submitted under a contract, loan guarantee or other agreement which was originally obtained by means of false statements or other corrupt and fraudulent conduct, or in violation of any statute or appropriate regulation, constitutes a false claim." S.Rep. No. 99-345 at 9 (1986), reprinted in 1986 U.S.C.C.A.M. 5266, 5274.

71. Section 3729(a)(1)(A) requires only that a claimant present a 'false or fraudulent claim for payment or approval' without the additional element of a 'false record or statement.' *Id.* Thus, § 3729(a)(1)(A) allows a relator to bring a claim based on a defendant submitting a claim for government funds without explicitly making a false statement.

B. Express Certification

72. The Medicare program requires approved providers to expressly and affirmatively certify that they have complied with the AKA. Failure to comply with the AKA, therefore, is, in and of itself, a false statement to the government.

73. Federal courts have determined in any case that compliance with the AKA is a precondition of payment. This conclusion is "rendered inescapable when the purpose of the AKA is considered within the context of the Medicare statute." 42 U.S.C. § 1395y(a)(1)(A).

Moreover, courts, without exception, agree that compliance with the AKA is a precondition of Medicare payment, such that liability under the FCA can be predicated on a violation of the AKA.[4]

74. Medicare regulations and the CMS Provider Agreement expressly provide that certification is a precondition to governmental reimbursement. In order to obtain reimbursement, and as a condition to payment, providers must certify that they are in compliance with the terms of the Provider Agreement.

75. AIS has maintained billing privileges with Medicare and has entered into a Provider Agreement CMS Form 855s. This Provider Agreement contains a certification that each provider must certify as follows:

> ". . . I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare."

76. AIS' actions violate the Federal FCA, 31 U.S.C. § 3729(a)(2) and § 3729(a)(1)(B) in that AIS knowingly and falsely certified that it had complied with the AKA in order to get claims paid by Federal Health Care Programs.

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[4] *See, e.g., Willis v United Health Group,* 2011 WL 2573380 (2011), ("Compliance with the [AKA] is clearly a condition of payment under Parts C and D of Medicare); *United States ex rel. Kosenske v. Carlisle HMA, Inc.,* 554 F.3d 88, 94 (3d Cir.2009) ("Falsely certifying compliance with the ... Anti–Kickback Act[ ] in connection with a claim submitted to a federally funded insurance program is actionable under the [False Claims Act]."); *United States ex rel. Schmidt v. Zimmer, Inc.,* 386 F.3d 235, 243 (3d Cir.2004) ("A certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program.")

VIII. CAUSES OF ACTION

A. Count One

The FCA: 31 U.S.C. § 3729(a)(1)(A)

77. The allegations of paragraphs 1-76 are incorporated herein as if more fully set forth at length.

78. The FCA, 31 U.S.C. § 3729(a)(1)(A) makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment a violation of federal law for which the United States may recover three times the amount of the damages the United States sustains and a civil monetary penalty of between $10,781 and $21,563 per claim.

79. The false statements by AIS regarding compliance with the AKA were an express false certification made by AIS in the claims submissions as well as in CMS Form 885A and CMS Form 1500.

B. Count Two

The FCA: 31 U.S.C. § 3729(a)(1)(B)

80. The allegations of paragraphs 1-79 are incorporated herein as if more fully set forth at length.

81. The FCA, 31 U.S.C. § 3729(a)(1)(B) makes "knowingly" making, using or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of $10,781 and $21,563.

82. The false statement contained in AIS' State Pharmacy Board applications and registrations regarding USP Standards and Section 503A was submission of a false record.

C. Count Three

Hamer v. AIS – 31. U.S.C. § 3730(h)

83. The allegations of paragraphs 1-82 are incorporated herein as more fully set forth at length.

84. Plaintiff was terminated in May 2022 within several weeks of making one or more of such complaints to one or more human resources representatives or in-house counsel for Defendant.

85. Also during his employment, in April 2022, Plaintiff was injured at work by exposure to cleaning solvents, suffering injury to his lungs, constituting a disability as an impairment of his major bodily function of respiration.

86. Apart from the actions and omissions of Defendant reflecting retaliation against Plaintiff on the basis of his opposition to practices of Defendant violating the FCA, Plaintiff, during his employment by Defendant, was subjected to discrimination on the basis of religion and disability, and to retaliation, in violation of Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act and the Texas Labor Code, under the following circumstances:

87. During his employment, Plaintiff was repeatedly subjected to questions and bigoted statements and conduct of representatives of Defendant based on his Jewish religion. Plaintiff complained of such anti-Semitism by representatives of Defendant to one or more human resources representatives of Defendant and also complained to one more human resources representatives or in-house counsel for Defendant, or both, of sexual harassment by a representative of Defendant at a work function as well as racist and homophobic comments by representatives of Defendant at other times. Plaintiff further complained to one or more human resources representatives or in-house counsel for Defendant, or both, of derogatory statements on

the basis of race about his wife and other employees of Defendant by representatives of Defendant. Plaintiff was terminated in May 2022 within several weeks of making one or more of such complaints to one or more human resources representatives or in-house counsel for Defendant.

88. Also during his employment, after Plaintiff was injured at work by exposure to cleaning solvents, suffering injury to his lungs, constituting a disability as an impairment of his major bodily function of respiration, Plaintiff complained and requested accommodation in the form of a respirator and otherwise, including after suffering additional injury in the course of continuing to work, as instructed by his superior, at the risk of impairment of his respiratory function, but the accommodations were denied and he was terminated within two weeks of his last report of disability and request for accommodations.

IX. RELIEF REQUESTED

89. Relator requests the following relief be imposed against Defendant:

(a) That the United States and State Plaintiffs be awarded three times the amount of damages which it sustained because of the acts of Defendant pursuant to §3729(a)(1)(A) through C of the FCA;

(b) That Defendant be held liable for civil penalties up to $21,563 but not less than $10,781 (as adjusted pursuant to § 3729 of the FCA and the Civil Penalties Act), to the United States for every act in violation of the FCA;

(c) That this Court award such interest as is available pursuant to the FCA.

(d) That in the event the United States intervenes in this action and takes over its prosecution, the Relator be awarded an amount for bringing this action on behalf of the United States of at least 15% but not more than 25% of the proceeds paid to the

United States resulting from the trial or settlement of the claim pursuant to § 3730(d)(1) of the FCA;

(e) That in the event the United States does not intervene in this action, the Relator be awarded an amount for brining this action for the United States of at least 25% but no more than 30% of the proceeds paid to the United States resulting from the trial or settlement of the claim, pursuant to § 3730(d)(2) of the FCA;

(f) That this Court award reasonable attorneys' fees, costs and expenses to Relator, which were necessarily incurred in bringing and prosecuting this case pursuant to § 3730(d)(1) or (2) of the FCA;

(g) That this Court award Plaintiff individually all of the relief to which he is entitled described in paragraphs 83 through 88; and

(h) That this Court award such other relief as it deems just, necessary and fair. Relator requests a trial by jury of all issues so triable.

Respectfully submitted,

Kilgore & Kilgore, PLLC

/s/ Robert E. Goodman, Jr.

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